

REMARKS

This Response is submitted in reply to the non-final Office Action mailed on March 7, 2007. No fee is due in connection with this Response. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-203 on the account statement.

Claims 9-26 are pending in this application. Claims 1-8 and 27-34 were previously withdrawn. In the Office Action, Claim 18 is rejected under 35 U.S.C. §112 and Claims 9-26 are rejected under 35 U.S.C. §103. For the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claim 18 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Patent Office alleges that the expression “systemic system” is unclear and that the specification does not define the scope of the expression. Applicants respectfully disagree with the Patent Office’s assertion.

Applicants respectfully submit that the term “systemic system” can refer, for example, to “systemic circulation” that is typically accomplished by parenteral (intravenous) or enteral (GI tract) administration. See, specification, page 1, lines 24-28. One having ordinary skill in the art would clearly understand that “systemic circulation” refers to the general circulation of the blood through the body. See also, The American Heritage® Dictionary of the English Language, Fourth Edition. Accordingly, an advantage of the present invention is to provide for increased absorption and bioavailability of delivered medicaments as compared to medicaments that are designed to be absorbed in the GI tract (enterally), while also providing a method for administering medicaments or agents to an individual that previously were administered parentally (intravenous). See, specification, page 7, lines 27-30 and page 8, lines 1-3. Further, the Examples refer to measuring medicament levels in subjects’ blood streams to determine absorption of the medicaments. See, specification, page 28, lines 18-23; page 31, lines 9-14; page 33, lines 15-19.

Therefore, because (1) “systemic circulation” is a clearly understood term, (2) Applicants seeks to improve upon the typical enteral and parenteral methods used to administer medicaments to systemic circulation, and (3) Applicants prove out the methods by measuring

medicament absorption in the general blood stream, one of ordinary skill in the art would clearly be apprised of the scope of Claim 18 upon reviewing the claim in view of the specification. See, MPEP 2173.05(b). Accordingly, Applicants respectfully request that the §112 rejection with respect to Claim 18 be reconsidered and the rejection be withdrawn.

In the Office Action, Claims 9-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of U.S. Patent No. 4,317,838 to Cherukuri et al. ("*Cherukuri*") and WO 99/44436 to Stahl ("*Stahl*"). Independent Claims 9 and 18 recite, in part, a product comprising a gum center and a coating comprising at least 50% by weight of the product. Applicants respectfully submit that, even if combinable, the cited references fail to disclose or suggest all the elements of the claims.

For example, *Cherukuri* fails to disclose or suggest a coating comprising at least 50% by weight of the product. Though the Patent Office alleges that *Cherukuri* does indeed disclose this limitation (see, Office Action, page 2), none of the weight percentages disclosed teach a coating comprising at least 50% by weight of the overall product. See, for example, *Cherukuri*, column 2, lines 40-55 ("by weight of the coating syrup"); column 3, line 50 – column 4, line 4 ("by weight of the dusting mix"); column 4, lines 50-55 ("by weight of the gum center"); column 4, lines 55-58 ("by weight of the coating"), and column 5, lines 43-47 ("by weight of the gum base"). Moreover, when actually referring to weight % coating in the total product, *Cherukuri* only discloses a level of 35% by weight coating in the coated chewing gum tablet. See, *Cherukuri*, column 4, lines 29-34 and column 7, lines 15-19.

Stahl fails to remedy the deficiencies of *Cherukuri*. The Patent Office relies upon *Stahl* for arguably teaching a medicament in the coating along with a sweetener, an element the Office Action admits *Cherukuri* lacks. See, Office Action, page 3. Therefore, *Stahl*, like *Cherukuri*, still fails to disclose or suggest a coating comprising at least 50% by weight of the product.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 9-26 be reconsidered and the rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY 

Robert M. Barrett

Reg. No. 30,142

Cust. No. 29156

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